

The Utility of Telemedicine in the Management Migraine: A Pilot Study

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Introduction and Purpose:

This is a pilot, proof-of-concept, study assessing the utility of telemedicine for follow-up care in a headache medicine practice.

Hypothesis: Telemedicine is a viable and effective method of delivering follow-up care to patients with migraine, leading to patient outcomes and patient satisfaction equivalent to in-person office visits.

Specific aims:

1. To pilot a telemedicine program in patients with migraine for one year as measured by the ability to complete the visits as scheduled
2. Develop transferrable clinical protocols for migraine visits with Telemedicine
3. Assess the impact of care (telemedicine vs. in-person visit) on migraine-related disability as assessed by the Migraine Disability Scale (MIDAS)
4. Rate the subjects' satisfaction with assigned care strategy using the modified Group Health Association of America's Consumer Satisfaction scale and a semi-structured interview
5. Assess the economic and competitive impact of telemedicine services for neurology patients in our region

Secondary outcomes:

1. Number of supplementary encounters required (in-person visits, telephone calls, emergency department visits, unplanned hospitalizations)
2. Time missed from work or daily activities to receive care (including travel time)
3. Patient scheduling, tardy visits, no shows, and physician productivity

Background:

Headache is a common disorder, affecting over 35 million Americans. The most frequently occurring, disabling headache type is migraine. Migraine is the second most cause of missed work days (absenteeism) in the U.S. It affects 18% of women, 6% of men and 6% of children, touching one in four families. Approximately 50% of individuals with migraine (2.5% of the US population) experience moderate to severe headaches impacting their employment, home and leisure/family activities.

Slightly less than half of Americans with migraine have not been officially diagnosed, and self-medicate using over-the-counter products and non-pharmacological treatment. Most patients who are diagnosed with migraine are managed by their primary care physician or gynecologist. While these practitioners may be able to successfully treat patients with relatively infrequent or mild migraines, those with complex or debilitating

headache conditions often seek care from a neurologist. Patients with the most challenging and difficult headaches may be referred to a headache specialist.

The University Council of Neurological Specialties (UCNS) has offered board certification for physicians in the area of Headache Medicine since 2006. There are currently 250 physicians in the U.S. who have additional qualifications in Headache Medicine; most are located in major urban areas. The relatively small number of headache specialists is unable to keep pace with the number of patients seeking their help, and most have waiting times ranging from weeks to months for a new patient appointment. Appointment availability for follow-up visits is often limited as well.

The complexity of migraine management, including assessment of the effectiveness and side-effects of multiple medications, providing education regarding the pathophysiology and management strategies of migraine, managing co-morbid conditions (e.g., other co-existing headache conditions, depression, anxiety, fibromyalgia, other chronic pain syndromes), monitoring patient adherence to therapy, reviewing headache diaries, prescribing controlled substances when appropriate, and urgent management of acute headache episodes is demanding and time-consuming. Thus, follow-up care of migraine patients generally requires visits at relatively frequent intervals (weeks to 2-3 months) in order to provide optimal care. From the patient's perspective, this requires a commitment of time and resources far exceeding the duration of the office visit. The hidden person costs for the patient for in-person office visits may include time missed from work or school, child care costs, the need for an accompanying person in cases of long distance travel or the inability to drive while suffering from a migraine, transportation and parking costs. The hidden costs disproportionately affect patients who live long distances from the physician's office, often those living in rural areas. The provider's office (particularly in the university setting) may require the navigation of a complex hospital layout, aggravation associated with parking in a busy environment, fluorescent lighting and noise, all stressors that may contribute to the development or worsening of a migraine. Lastly, missed visits occurring because of illness or inclement weather may be difficult to reschedule in a timely fashion in a busy practice, leading to lapses in care.

Telemedicine is a medium that has potential benefits in a headache medicine practice. In particular, it lends itself to the follow-up management of patients once they have been evaluated in person at the initial visit. The initial evaluation of a patient with migraine includes a detailed history and physical examination to exclude a secondary cause of headache, such as tumor, intracranial hypertension, infection, inflammation or malignancy. The initial examination includes a neurological examination, with emphasis on the examination of the ocular fundi. The technology exists to perform the ophthalmic examination remotely from a centralized location using a technician or physician extender, but does not lend itself to use in non-medical settings.

The follow-up visit generally requires very little in the way of physical examination, as most time is spent in conversation reviewing the interim history, assessing response to treatment, discussing the need for additional testing, suggesting additional pharmacological and non-pharmacological therapeutic options, counseling and educating the patient, and prescribing the decided course of action. The average duration of a follow-up visit is 15-30 minutes. If the initial evaluation failed to disclose an abnormality on the examination, it is highly unlikely that the neurological examination in a subsequent encounter would demonstrate new findings in the absence of a change in the patients' symptoms. With supplementation of vital signs, which could be obtained

and recorded by the patient prior to the visit (or electronically at the time of the visit), telemedicine offers the opportunity for remote face-to-face contact between the patient and the physician, eliminating almost all of the patient's hidden costs associated with an in-person office visit, and avoiding delays and missed visits related to transportation and inclement weather. The additional anxiety often associated with an office visit may be reduced as patients will be able to interact with the physician from a convenient and comfortable setting while maintaining the "face-to-face" dynamic that is so important to the doctor-patient therapeutic alliance.

This is a pilot, proof-of-concept, study assessing the utility of telemedicine for follow-up care in a headache medicine practice.

Concise Summary of Project:

Consecutive patients undergoing their initial evaluation for headache at the Headache and Facial Pain Program at UT Southwestern, and meeting ICHD-2 criteria for migraine will be asked to participate in the study to achieve a total of 40 evaluable subjects (20 per group). All subjects will have their initial evaluation in person and those who agree to participate will be randomly assigned to either the telemedicine group or in-office group. Treatment will be determined by the P.I. on an individual basis as per usual standards of practice. All subjects will have the same number of follow-up encounters during the course of a year, and complete the same questionnaires throughout the study.

Study Procedures:

After obtaining informed consent, patients will be randomly assigned to receive their follow-up care via telemedicine or in-office visits. All subjects will complete a MIDAS questionnaire and allodynia questionnaire at their initial visit. Follow-up visits will be scheduled at 4-6 weeks, 3, 6, 9 and 12 months. In-person follow-up visits will be conducted in the standard fashion of the current physician's practice, with the initial intake conducted by an ophthalmic technician or resident, followed by the physician visit. Telemedicine visits will be conducted by the physician and audio and video recorded. Similar information will be gathered in both groups including: current medications, interim medical and headache history (including visits to the ED or hospitalizations for headache), description of headache, response to treatment (including adverse reactions), allergies, blood pressure and weight. Subjects randomized to telemedicine will be asked to have their blood pressure and weight measured within 5 days of their telemedicine session at a location convenient to them. We will record the length of each visit. Subjects in the in-person group, will be queried about travel time, and the total amount of time for the visit, and any activities missed to attend the visit. We will also ask about other costs associated with attending the office visit, such as child care.

At the one-year follow-up visit, subjects will complete the MIDAS, allodynia questionnaire, Modified Group Health Association of America's Consumer Satisfaction scale, and have the opportunity to express their views on the aspect of care received in a semi-structured interview. The follow-up questionnaires may be completed on line (telemedicine group, optional for in-person group) or on paper (in-person group). Headache diaries will be provided on line or may be done on paper, a smartphone, or a computer program of the subject's choosing.

All subjects will be able to access the physician by telephone, using MyChart, or with additional non-study visits as needed.

Subjects will be responsible for the cost of the medications, treatments prescribed, and laboratory monitoring needed for their condition.

Support staff will be available to help set up the video system for subjects assigned to the telemedicine group who are in need of assistance.

In order to obtain 40 evaluable subjects, it is anticipated that approximately 50 subjects will be consented. Participation will last approximately 13 months, to allow time to set up and complete to post-study interview. Subjects may be dismissed from the study if they fail to carry out study procedures or may exit the study by withdrawing consent. After the study period, subjects will continue their care in the practice with in-person office visits.

All subjects will be compensated equally for their time and for completing the study assessments. Every attempt has been made to make the two study arms equivalent in terms of financial outlay and subject compensation. We anticipate that the telemedicine option will be perceived as more convenient than the in-person visit. The study will supply the web camera (approximate value \$25) and any software support needed for accessing the telemedicine system. The study will pay the co-payments for the in-person group so they will not have any out-of-pocket expenses related to the visit charge for their follow-up visits. We will cover travel and parking expenses for the in-person group.

Criteria for Inclusion of Subjects:

- Ages 18 – 89 years
- Diagnosis of migraine with or without aura, menstrual migraine, hemiplegic migraine
- Able to provide informed consent
- Able, in the opinion of the investigator, to reliably perform all aspects of the study
- Ownership of or access to a computer and high speed internet

Criteria for Exclusion of Subjects:

- Age less than 18 years
- Headache type is not migraine
- No ownership or access to a computer or high speed internet
- Unfamiliar with basic computer operations or uncomfortable using a computer
- Unwilling to participate
- Unable to read English (because of assessment tools)
- History of another medical, psychiatric, social or behavioral problem that, in the opinion of the investigator, makes it unlikely that they will be able to complete the study activities. Questions regarding mood and anxiety are asked of all patients as part of their initial evaluation for headache.

Sources for Research Material:

Information will be used from the questionnaires mentioned, post-study interviews, and the subjects' medical records. The medical record, accessed for the one year period of participation, will primarily be used to determine interim ED visits and hospitalizations for headache. The telemedicine visits will be recorded and information from those recordings may be used for research purposes.

Recruitment and Consenting Process:

Potential subjects will be approached during or immediately after their initial examination for migraine treatment. Potential subjects will be identified from referral information to the Headache and Facial Pain Program. The consent process will occur during or shortly after their initial clinic visit, after it is determined that they meet ICHD-2 criteria for migraine. All eligible patients will be asked to participate.

Potential Risks and Benefits:

This is a minimal risk study as the risk is no greater than that associated with a routine visit to the physician or standard treatment for migraine.

Psychological Stress

Subjects may be asked questions that are personal and may make them feel uncomfortable or upset. Subjects may refuse to answer any of the questions, take a break or stop their participation in this study at any time.

If Subjects are assigned to telemedicine visits, there is a risk to their privacy as the information is sent over a high-speed computer connection. We will do our best to protect their privacy by using special coding and protections to our computer systems.

Loss of Confidentiality

Any time information is collected; there is a potential risk of loss of confidentiality. Every effort will be made to keep subject information confidential; however, this cannot be guaranteed.

Subject Safety and Data Monitoring:

Any adverse events related to treatments prescribed as part of routine care will be handled by the P.I., her colleagues and staff at the Headache and Facial Pain Program in a timely manner. The P.I. will receive communication regarding any adverse events through Epic, and is responsible for safety and data monitoring.

Procedure to Maintain Confidentiality:

Subjects will be assigned a study number which will be used for study data collection and analysis. Medical records are stored in the Epic system. Case report forms (paper) will be kept in a locked and secure cabinet. No identifying data will be entered into the data set used for analysis. All information obtained on line and video recordings will be stored using encryption and password protection. Videotapes will not be obtained or used without the subject's permission. The subject's address will be used to calculate the distance from their home to UTSW and will not be retained in the study materials.

Potential Benefits:

All subjects may benefit from participation as they will be evaluated by the physician more frequently than in routine practice. There may or may not be a benefit from telemedicine participation as compared to in-person care.

We hope the information learned from this study will benefit others with migraine in the future. Information gained from this research could lead to better care and treatment of migraine, especially for people who live in a remote area or have limited access to a headache specialist.

Biostatistics:

Excel 2016 and R (version 3.5.2) were used to perform the statistical analysis. The primary outcome measure was the percentage of visits using telemedicine completed as scheduled; the sample size was chosen to provide evidence for this proof of concept.⁵ Secondary outcome measures included clinical outcomes related to headache disability (MIDAS, number of headache days in the last 3 months, and severity on a scale of 0-10 with 10=pain which is as bad as it can be), visit time, and perceptions of telemedicine. The average change from baseline to 12 months for the in-office group was compared with the average change for those in the telemedicine group (difference in average difference). The McNemar χ^2 test was used to examine differences in the proportion of participants reporting moderate to severe disability (MIDAS ≥ 11) between the baseline and 12 months.⁶ Logistic regression was used to test whether membership in the in-office group was associated with experiencing a 50% or greater improvement in clinical outcomes. The logistic regression was also controlled for baseline values. Two sample t-tests were used to estimate whether participants in different groups differed in their survey responses.

REFERENCES:

1. Biglan KM, Voss TS, Deuel LM, et al. Telemedicine for care of nursing home residents with Parkinson's disease. *Movement Disorders* 2009;24(7):1073-1075.
2. Hersh WR, Hickam DH, Severance SM, et al. Diagnosis, access and outcomes: Update of a systematic review of telemedicine services. *J Telemed Telecare* 2006;12 Suppl 2:S3-31.
3. García-Lizana F, Muñoz-Mayorga I. Telemedicine for depression: a systematic review. *Percept Psychiatr Care* 2010 Apr;46(2):119-26.